

Notice of Allowability

Application No.

10/008,960

Examiner

Stephen Gucker

Applicant(s)

SMITH ET AL.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/5/04.
2. ☒ The allowed claim(s) is/are 22-39, renumbered as 1-18, respectively.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5/3/04 + 12/20/02
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.

7. ☒ Examiner's Amendment/Comment

same document

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.

EXAMINER'S AMENDMENT & REASONS FOR ALLOWANCE

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Margaret B. Kelly on 6/11/04.

An examiner's amendment to the record appears below.

In the specification:

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Cancelled the abstract.

Inserted this abstract after the claims:

C₁
--Polyclonal and monoclonal antibodies that specifically bind senescent cell derived inhibitor protein (SDI-1), cell lines that produce such monoclonal antibodies, and the use of such antibodies are disclosed.--.

On page 1, line 20, deleted "pending" after "October 24, 1994 and now". ✓

On page 1, line 20, inserted after "October 24, 1994 and now":

--US 6,372,249--.

On page 77, line 33, after "07/808,523" inserted:

--, now abandoned,--.

On page 78, line 2, after "07/808,523" inserted:

--, now abandoned--.

In the claims:

22. (Currently Amended) An antibody to a senescent cell-derived inhibitor, SDI-1, which antibody specifically binds to an SDI-1 fusion protein, which protein comprises (i) an SDI-1 protein comprising the amino acid sequence shown as SEQ ID NO:2 or fragment thereof and (ii) a hinge region of at least the amino acids depicted in SEQ ID NO:9, which fusion protein is capable of inhibiting DNA synthesis in a recipient cell.

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~~24.~~ (Currently amended) An antibody to a senescent cell-derived inhibitor, SDI-1, which antibody specifically binds to an SDI-1 fusion protein comprising the amino acid sequence depicted in [SEQ ID NO:11] SEQ ID NO:2.

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~~25.~~ (Currently amended) An antibody to a senescent cell-derived inhibitor, SDI-1, which antibody specifically binds to the SDI-1 protein encoded by [SEQ ID NO:2] SEQ ID NO:1.

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~~28.~~ (Currently amended) A monoclonal antibody to a senescent cell-derived inhibitor, SDI-1, which antibody specifically binds to:

- a) a protein [comprising] having the coding sequence of the cDNA insert of the plasmid contained in ATCC Deposit 69081;
- b) a fusion protein [comprising] having at least the coding sequence of the cDNA insert of the plasmid contained in ATCC Deposit 69081;
- c) a fusion protein encoded by a sequence consisting of the coding sequence of the amino acid sequence depicted in [SEQ ID NO:11] SEQ ID NO:2;
or
- d) a fusion protein encoded by a sequence consisting of the coding sequence of the cDNA insert of the plasmid contained in ATCC Deposit 69597.

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31. (Currently amended) A continuous cell line prepared by fusing a tumor cell with an antibody-producing cell derived from a mouse immunized with a protein which is a senescent cell-derived inhibitor, SDI-1, comprising the amino acid sequence shown as SEQ ID NO:2, or a fragment thereof.

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32. (Currently amended) A continuous cell line which produces a monoclonal antibody specific for a protein which is a senescent cell derived inhibitor, SDI-1, comprising the amino acid sequence shown as SEQ ID NO:2, or a fragment thereof, wherein the continuous cell line is prepared by fusing a myeloma or plasmacytoma cell with a splenic leukocyte derived from a mouse immunized with an SDI-1 protein or fragment thereof.

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37. (Currently amended) A [pharmaceutical] composition which comprises the SDI-1 antibody of Claim ^{1 2 3 4 5 8 9}~~22, 23, 24, 25, 26, 29 or 30~~ in a pharmaceutically acceptable carrier.

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38. (Currently amended) A [pharmaceutical] composition which comprises the SDI-1 monoclonal antibody of Claim ^{6 7}~~27 or 28~~ in a pharmaceutically acceptable carrier.

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¹⁸
~~39~~. (Currently amended) A process for detecting the presence of a protein which is a senescent cell-derived inhibitor, SDI-1[,] protein, comprising the amino acid sequence shown as SEQ ID NO:2, or a fragment thereof, which process comprises the steps of:

- (a) contacting a sample with a soluble antibody to the SDI-1 protein or fragment thereof; and
- (b) detecting the presence of the SDI-1 protein, or fragment thereof, bound to the antibody.

2. The following is an examiner's statement of reasons for allowance: the closest prior art of record is Biesinger et al. Biesinger et al. disclose an open reading frame (ORF) for an *Herpesvirus saimiri* strain that shares a seven amino acid region with SEQ ID NO:2 (residues 129-135 of SEQ ID NO:2 are identical to residues 13-19 of ORF 3 of Biesinger et al., page 507). However, Biesinger et al. do not teach any antibodies to any disclosed sequence, and Biesinger et al. do not provide any teachings by which residues 13-19 of ORF 3 could be considered as an obvious or suggested immunogen by one of ordinary skill in the art in order to make antibodies to that specific putative epitope of ORF 3 of *Herpesvirus saimiri*, as compared to any or all other putative epitopes found within the ORF 3 of *Herpesvirus saimiri*.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should

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preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


3. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.



Stephen Gucker

June 12, 2004


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600